JUN 1 4 2004 STATES PATENT AND TRADEMARK OFFICE

In re Application of: Denis MARTIN et al.

Serial No.: 10/650,123

Group Art Unit: 1646

Filed: August 28, 2003

Examiner: Not Yet Assigned

For: PHARMACEUTICAL COMPOSITIONS

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§ 1.56, 1.97 and 1.98

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

This information disclosure statement is made in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98 as follows:

Timing and Fees

\boxtimes		nder 37 C.F.R. § 1.97(b), no fee or statement is required for filing this information sclosure statement is filed:			
			three months of the filing date of a national application other than a CPA § 1.53(d);		
2.			three months of the actual filing date of the national phase of a PCT ration; OR		
	\boxtimes	before RCE)	e the mailing of a first substantive office action (including after filing of an		
			.R. § 1.97(c), this information disclosure statement is filed after the periods 7 C.F.R. § 1.97(b), but before the mailing date of:		
			a final rejection under 37 C.F.R. 1.113;		
			termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR		
			a notice of allowance under 37 C.F.R. § 1.311; and		

		is acco	ompanied by:
			the statement as specified in 37 C.F.R. § 1.97(e) set out below; OR
			a check covering the fee of \$180.00 under 37 C.F.R. § 1.17(p).
			R. § 1.97(d), this information disclosure statement is filed after the mailing lowing actions which have not been withdrawn:
			a final action under 37 C.F.R. § 1.113;
			termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR
			a notice of allowance under 37 C.F.R. § 1.311;
	AND	is filed o	on or before payment of the issue fee; AND is accompanied by:
			the statement as specified in 37 C.F.R. § 1.97(e) as set forth below, and the fee of \$180.00 under 37 C.F.R. § 1.17(p).
Staten	nents U	nder 37	C.F.R. 1.97(e)
			Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application having a mailing date not more than three months prior to the filing date of this information disclosure statement; or
			No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned attorney after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing date of the information disclosure statement.
Cited 1	Materia	<u>ls</u>	
		ancesto	of materials listed but not attached were cited in benefit (35 U.S.C. § 120) or application Serial No, on Form 892 by the Examiner and/or Form y the applicant; see 37 C.F.R. § 1.98(d).
			of materials listed but not attached were cited in an international search dated
	\boxtimes	Copies	of the materials listed are attached.

Non-Er	nglish I	Language References
	\boxtimes	An English-language search report or equivalent paper from a foreign patent office is provided indicating the relevance of the cited reference(s).
		A foreign-language search report from a foreign patent office is provided, and pertinent parts are translated substantively below:
		 X = document of particular relevance when it is taken alone Y = document of particular relevance when it is combined with another such document
		A = document defining the general state of the art
		O = non-written disclosure
		P = intercalated document
		T = document cited to understand the theory or principle underlying the invention
		E = patent document which has the benefit of a date earlier than the filing date and which was published only on or after this filing date
		D = cited in the application
	•	L = cited for another reason
		& = publication of member of same patent family
		Translation of other relevant information on foreign search report
Other In	nforma	<u>tion</u>
Paymer	nt of Fe	es Due (If Any):
		k for \$ covering the fee identified above is attached.
	Please	charge to Deposit Account No. 13-3402 \$ for the fee identified above.

The Commissioner is hereby authorized to charge or credit any overpayment to Deposit Account #13-3402, two copies of this paper are attached for this purpose.

Respectfully submitted,

Richard M. Lebovitz, Reg. No. 37,067 Attorney for Applicants

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
Arlington Courthouse Plaza I 2200 Clarendon Blvd. Suite 1400 Arlington, Virginia 22201 Telephone: (703) 243-6333

Facsimile: (703) 243-6410

Attorney Docket No.: PHARMA-0330

Date: June 14, 2004

RML:jmj

Please type a plus sign (+) inside this box

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

TA TRADEN Under the Paperwork Reduction Act of 1995, no pe red to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

3

Sheet of

Complete if Known				
Application Number	10/650,123			
Filing Date	August 28, 2003			
First Named Inventor	Denis MARTIN et al.			
Group Art Unit	1646			
Examiner Name	Not Yet Assigned			
Attorney Docket Number	PHARMA-0330			

			ATENT DOCUMENTS	
Cite No.1	U.S. Patent Docum	ent Kind Code ² (<i>if known</i>)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
	6,287,574	B1	Brodeur B.R. et al.	9-11-2001
		 		
		-		

-				
		<u> </u>		
	Cite No.1	Cite No.1 Number	Kind Code ² Cite No. ¹ Number (<i>if known</i>)	Kind Code ² Name of Patentee or Applicant Cite No. ¹ Number (<i>if known</i>) of Cited Document

	FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No.1	Office ³	Foreign Patent Docur Number ⁴	nent Kind Code ⁵ (<i>if known</i>)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		wo	99/52549	Α	Smithkline Beecham	10-21-1999	Pages 31-33	
		wo	94/05703		Global Tek, Inc.	3-17-1994		

Examiner Signature	Date Considered	

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO Complete if Known Application Number 10/650,123 INFORMATION DISCLOSURE August 28, 2003 Filing Date STATEMENT BY APPLICANT Denis MARTIN et al. First Named Inventor Group Art Unit (use as many sheets as necessary) Not Yet Assigned **Examiner Name** Attorney Docket Number PHARMA-0330 Sheet of

		NON PATENTILITERATURE DOCUMENTS.	. x. 4a
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Т,
		Denis Martin et al., J. of Biotechnology (2000), Vol. 83 No. 1-2, pp. 27-31, "Candidate Neisseria meningitidis! NspA vaccine"	
		Tania Carmenate et al., Biotechnology and Applied Biochemistry 2001, Vol. 34, No. 1, pp. 63-69, "Recombinant Opc protein from <i>Niesseria meningitides</i> reconstituted into liposomes elicits opsonic antibodies following immunization"	
		Christodoulides et al., Microbiology (1998) 144, No. 11, pp. 3027-3037, "Immunization with recombinant class 1 outer-membrane protein from <i>Neisseria meningitidis</i> : Influence of liposomes and adjuvants on antibody avidity, recognition of native protein and the induction of a bactericidal immune response against meningococci"	
		D. Martin et al., Poster no 672 presented in Oslo, Norway in Sept. 2002. "Recombinant NspA incorporated into liposomal vesicles induces functional antibodies"	
		Claudio Tavares Sacchi et al., "Considerations on the use of <i>Neisseria meningitidis</i> class 5 protein as meningococcal BC vaccine components," Vaccine 1995 Vol. 13, pp. 112-118,	
		Colin R. Tinsley et al., J. of General Microbiology 1992 138, 2321-2328. "Antibodies recognizing a variety of different structural motifs on meningococcal Lip antigen fail to demonstrate bactericidal activity"	
		G.R. Moe et al., Infection and Immunity, June 2001, Vol. 69 No. 6, pp. 3762-3771, "Functional Activity of Anti-Neisserial Surface Protein A Monoclonal Antibodies against Strains of Neisseria meningitidis Serogroup B"	
		Victor C. Hou et al., Infection and Immunity, Dec. 2003, Vol. 71, No. 12, pp. 6844-6849, "Conformational Epitopes Recognized by Protective Anti-Neisserial Surface Protein A Antibodies"	
		Lucy Vandeputte-Rutten et al., The Journal of Biological Chemistry, July 4, 203, Vol. 278, No. 27, pp. 24825-24830, "Crystal Structure of Neisserial Surface Protein A (NspA), a Conserved Outer Membrane Protein with Vaccine Potential"	
		Gregory R. Moe et al., Infection and Immunity Nov. 2002, Vol. 70, No 11. pp. 6021-6031, "Sequential Immunization with Vesicles Prepared from Heterologous Neisseria meningitidis Strains Elicits Broadly, etc."	
		D. O. Koroev et al., Russian J. of Bioorganic Chemistry, Vol. 28, No. 4, 2002, pp. 263-268. "Induction of Antimeningitis by synthetic Peptides: III. Immunoactive Synthetic Fragments of the NspA Protein from Neisseria meningitidis"	
		Carmen Arigita et al., Vaccine 21 (2003) pp. 950-960, "Restored functional immunogenicity of purified meningococcal PorA by incorporation into liposomes"	
		J. Claire Wright et al., Infection and Immunity, August 2002, p. 4028-4034 Vol. 70, No. 8, "Immunization with Recombinant PorB Outer Membrane Protein Induces a Bactericidal Immune Response against Neisseria meningitidis"	
		Carmen Arigita et al., Infection and Immunity, Sept 2003, p. 5210-5218, Vol. 71, No. 9, "Liposomal Meningococcal B Vaccination: Role of Dendritic Cell Targeting in the Development of a Protective Immune Response"	

Keith A. Jolley et al., Infection and Immunity, June 2001, p. 3809-3916, Vol. 69, No. 6, "Immunization with Recombinant Opc Outer Membrane Protein from Neisseria meningitidis: Influence of Sequence Variation and Levels of Expression on the Bactericidal Immune Response against Meningococci"
Idanpaan-Heikkila et al., Vaccine 1995, Vol. 13, No. 16, pp. 1501-1508, "The antibody response to a prototype liposome vaccine containing Neisseria meningitidis outer membrane protein P1 produced in Bacillus subtilis"
Manjeet M. Parmar et al., Vaccine 1997, Vol. 15, No. 15, pp. 1641-1651, "Biophysical and antigenic characterization of gonococcal protein I incorporated into liposomes"
Immunogenicity of recombinant class I protein from Neisseria meningitidis refolded into phospholipids vesicles and detergent, Olivia Niebla et al., Vaccine 19 (2001) 3568-3574
Stephen J. Ward et al., Microbial Pathogenesis 1996; Vol. 21, pp. 499-512. "Expression of Neisseria meningitidis class 1 porin as a fusion protein in Escherichia coli: the influence of liposomes and adjuvants on the production of a actericidal immune response"
Sara L. Morley et al., Vaccine (2002) Vol. 20, 666-687, "Vaccine prevention of meningococcal disease, coming soon?"
Clementien L. Vermont et al., Current Opinion in Molecular Therapeutics 2003, Vol. 1, pp 33-38, "Recent developments in vaccines to prevent meningococcal serogroup B infections"
Bethell & Pollard, "Meningococcal Vaccines", , Expert Rev. Vaccines 1(1) (2002), pp. 75-84
Einar Rosenqvist et al., "The 5C Protein of <i>Neisseria meningitidis</i> Is Highly Immunogenic in Humans and Induces Bactericidal Antibodies", J. Infectious Diseases (1993), 167: pp. 1065-1073

Examiner	Date	
Signature	Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.